AMENDMENTS TO THE DRAWINGS

Figures 1, 3, 4, and 5 have been amended to replace filled-circles with empty circles as indicated in the Office Action.

REMARKS

The amendment of September 11, 2008 was not entered on the grounds that it was non-compliant, as per the United States Patent and Trademark Office communication dated August 5, 2009. Accordingly, the claims are marked-up relative to the last amendment that was entered, on March 10, 2008. This Amendment addresses the rejections in the nonfinal office action dated June 11, 2008 (the Office Action).

The Drawings have been amended as indicated above. Acceptance of the drawings is requested.

The specification has been amended as indicated above. Acceptance of the specification is requested.

Claims 34, 38, 39, 41-42, 49, 57, 61, 64-67, and 95-105 are pending. Claims 36 and 56 are cancelled herein. Claims 34, 41, 42, 57, 61, and 64-66 have been amended. New claims 95-105 were added. Claims 36, 38 and 56 were cancelled.

Claim 34 was amended to state a thickness of at least 50 microns as at, e.g., the last full paragraph of page 34. Further support for the amended claim may be found, e.g. at page 8 lines 1-7 (polysaccharide macromers in solution to make cross-linked hydrogel) and the paragraph bridging pages 9-10 (polysaccharide macromers made in organic solvent). The term macromer is defined at page 17 lines 7-10 ("A macromer, as used herein, is a monomer or a polymer that is polymerizable and is a convenient term for referring to monomers or polymers that have been decorated with a monomer or used as decorations."). The term hydrogel is defined at page 18 lines 1-9.

Claims 41, 42, 57, 61, and 64-66 were amended for antecedent basis.

New claim 95 recites the medical device as a knitted tube, e.g., as at Example 11 (page 63).

New claim 96 recites using a mandrel in the context of the knitted tube, e.g., as at Example 11.

New claim 97 recites using a mold in the context of the knitted tube, e.g., as at page 23 lines 18-23 & page 26 line 23 (tubular member as a fabric).

New claim 98 recites the embodiment of claim 97 with heparin polysaccharides having at least 5 units per 100 mm2 activity and the hydrogel with a water content of at least about 50%, e.g., as at Example 11.

New claim 99 recites at least 80% heparin, e.g., as at page 8 line 12.

New claim 100 recites a hydrogel of at least about 500 microns in thickness, as at, e.g., page 34 line 16.

New claim 101 is directed to polymerization of polysaccharide macromers with other macromers, e.g., as at page 20 lines 14-18 or page 24 lines 4-5. The term synthetic is defined at page 2 lines 8-10.

New claims 102-103 are directed to particular macromers, e.g., as at page 24 line 10 to 23 and page 25 line 8 (polyvinyl pyrrolidone functionalized with methacrylate groups, claim 102).

New claim 104 is directed to particular vinylic monomers on the macromers, e.g., as at page 44 line 15.

RELATED APPLICATION

Please note that U.S. Serial No. 10/179,453 is a parent of the present case and implicates many of the same issues, cites potentially relevant art, and also has some arguments that are potentially related. This other application is presently being examined by the same Examiner. The art and office actions in this other case can be submitted via IDS if desired by the Examiner; the Examiner is assumed to be aware of the full and complete record of this other application via his work and through PAIR.

REJECTIONS

Claims 34, 36, 38, 39, 41, 42, 49, 56, 57, 61, and 64-67 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yafuso et al. (U.S. Pat. No. 5,583,213) in view of Shah et al. (U.S. Pat. No. 6,248,127), Sahatjian (U.S. Pat. No. 5,135,516), WO 97/41164, WO 0013719, Guire et al. (U.S. Pat. No. 5,512,329) and Hsu (U.S. Pat. No. 5,417,969), collectively referred to herein as the Cited References.

Grounds of Traversal

The rejection is respectfully traversed on the grounds that the rationale does not provide a basis for the presently claimed items:

i. preparing polysaccharide macromers from a polysaccharide complex in an organic solvent;

ii. forming a hydrogel

iii. forming a 50+ micron-thick hydrogel

iv. polymerizing polysaccharide macromers to form the hydrogel

• Please note that each of points i-iv are dispositive.

Argument

The prior art must provide every claimed feature. The following features, however, are not provided with respect to the present claims:

i. preparing polysaccharide macromers from a polysaccharide complex in an organic solvent;

ii. forming a hydrogel

iii. forming a 50+ micron-thick hydrogel

iv. polymerizing polysaccharide macromers to form the hydrogel

• Yafuso et al. (U.S. Pat. No. 5,583,213) teaches a solid-phase chemical approach to making a complex, with a polysaccharide being passed over a solid-phase column of quaternary salts that bind the polysaccharide (column 5 lines 41-58). In contrast, the claimed method uses solution-phase chemistry that is simpler and advantageous. Further Yafuso does not make a polysaccharide macromer having polymerizable vinylic groups. Further, Yafuso does not teach or suggest making a hydrogel or reacting polysaccharide macromers with each other, but instead teaches activating polysaccharide and reacting them with a surface, e.g., column 5 line 45 to column 6 line 3. This reference does not teach or suggest presently claimed items i-iv.

• Shah et al. (U.S. Pat. No. 6,248,127) uses an approach like Yafuso, with heparin complexes (of unknown preparation history) being activated with silanes that are then used to form covalent bonds with a surface (e.g., column 3 lines 21-46). Shah et al. does not make a polysaccharide macromer having polymerizable vinylic groups. Further, Shah et al. does not

teach or suggest making a hydrogel or reacting polymerizable vinylic polysaccharide macromers with each other. This reference does not teach or suggest presently claimed items i-iv.

• Sahatjian (U.S. Pat. No. 5,135,516) relates to a thin coating on a surface (Abstract, therein). The heparin is bound directly to the surface by electrostatic attraction. This reference does not teach or suggest presently claimed items i-iv.

• WO 97/41164 provides heparin macromers that are used as an ingredient to make other polymers that are then applied to a surface (e.g., at page 12, last ¶). WO 97/41164 does not teach or suggest polymerizing the vinylic groups of the polysaccharide macromers with each other to form a covalently-crosslinked hydrogel with a thickness of at least 50 microns on the device. Further, the WO 97/41164 heparin macromers are prepared by decoration of heparin with monomers in aqueous solutions so that the structure of the resultant polysaccharide macromers is inherently not the same as the claimed polysaccharide macromers prepared in organic solvent. WO 97/41164 relates to coating a surface with antithrombogenic materials, without building up a hydrogel., e.g., see working Example 16. This reference does not teach or suggest presently claimed items i-iv.

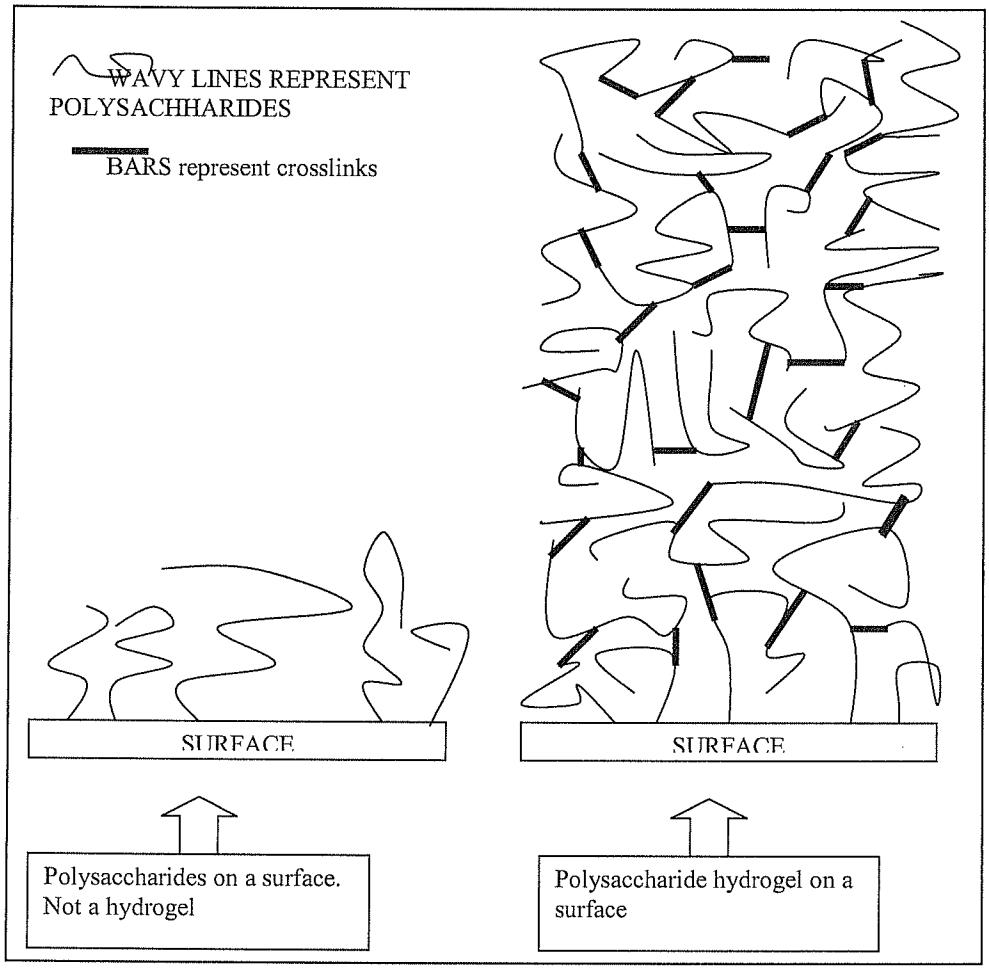
• WO 0013719 apparently relates to adsorbing heparin to a surface, see Example 2 therein. Mere adsorption is not claimed, nor is unmodified heparin claimed (see Example 1 of WO 0013719)

• Guire et al. (U.S. Pat. No. 5,512,329) describes coating a surface with reactable polysaccharide and then reacting the polysaccharide to form covalent bonds. This reference does not teach or suggest presently claimed items i-iv.

• Hsu (U.S. Pat. No. 5,417,969) relates to coating a surface and exposing it to ionizing radiation to thereby link the material to the surface, e.g., Abstract therein. This reference does not teach or suggest presently claimed items i-iv.

The Application details important points of distinction between the claimed hydrogels and other materials. A hydrogel is a cross-linked material that can absorb or imbibe a water and is produced by the cross linking of one or more monomers or polymers (Application page 18 lines 8). In contrast, polysaccharides that merely react with a surface (as in the Cited References) are not forming a hydrogel.

The illustration below exemplifies structural distinctions between a hydrogel and merely reacting a polysaccharide with a surface:



The present claims are directed to building up a hydrogel of substantial thickness. In contrast, the cited references are apparently focused on reacting a material directly to a surface.

The properties of the invention as a whole.

Legal Principles

Central to the obviousness examination is that the claimed invention is to be examined as a whole, **meaning that its properties are inseparable** from the claimed components. This means that the claimed components must be found in the prior art along with a rationale for combining them in the same way *to have the same properties*. The Federal Circuit has explained:

> "An analysis of obviousness of a claimed combination must include consideration of the results achieved by that combination. As we explained in *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed.Cir.1985): ***Critical to the analysis is an understanding of the particular results achieved by the new combination.*** The claims here at issue are directed to a combination of known components of telephone systems in an admittedly new way to achieve a new total system. Neither the district court in its opinion, nor the defendants, identified any suggestion in the prior art that the components be combined as they were by [the inventor] or that such combination could achieve the advantages of the [claimed] system.
>
> We see no reason why the above reasoning from *Interconnect*, a case that dealt with a mechanical invention, should not apply with equal weight to the present chemical case. There is no question that each component of Monson's composition was separately known in the prior art. What was not known or suggested, however, was the composition that resulted from the combination of those components, and its unique properties. As Johnson succinctly states, The Monson invention is a post-foaming gel composed of four components, all of which interact to provide a particular kind of gel with suitable shaving characteristics-in fact, shaving properties superior to any other product on the market. ***The invention as a whole is that composition, with its gel form, and its properties.***"
>
> *Gillette v. .C. Johnson & Son, Inc.* 919 F.2d 720, 725, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990), emphases added.

KSR has not altered these principles:

> "The determination of obviousness is made with respect to the subject matter as a whole, not separate pieces of the claim. See KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 127 S.Ct. 1727, 1734, 167 L.Ed.2d 705 (2007); Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1448 (Fed. Cir. 1984). For chemical compounds, the structure of the compound and its properties are inseparable considerations in the obviousness determination. See In re Sullivan, 498 F.3d 1345, 1353 (Fed. Cir. 2007); In re Papesch, 50 C.C.P.A. 1084, 315 F.2d 381, 391 (1963)." Sanofi-Synthelabo v. Apotex Inc., 550 F.3d 1075, 1086, 89 U.S.P.Q.2d 1370 (Fed. Cir. 2008).

Analysis

The present invention, when considered as a whole, has properties that are not found in, and do not flow from, the Cited References or prior art.

One property of the claimed polysaccharide hydrogel is that it is thick, e.g., the claimed 50+ microns. Thick films have advantages in that they may be punctured by sutures and suffer scratches and damages to their surface without losing their favorable blood-contacting properties. See Application, ¶ bridging pages 22-23. Further, a thick film can offer superior surface coverage and activity compared to a thin coating on a surface because the efficiency of surface chemistry reactions could provide a surface coverage of less than 100%, i.e., not every space on a surface coated with heparin is completely covered with a heparin molecule. See Application, page 23, first full ¶.

Moreover, the claimed polymerization process provides for a distinct physical structure not comparable to activated polysaccharides reacting directly with a surface, as in the illustration above.

Furthermore, a hydrogel structure characterized by polymerization of vinylic groups in solution has properties distinct from other processes since the polysaccharide macromers are

polymerized in solution. A process of drying, aggregating, or coacervating polysaccharides followed by crosslinking is not comparable. See Application page 21 line 14 to 20. Indeed, scanning electron microscopy studies showed that the process does form a true three-dimensional structure, See Application Example 16 (last sentence).

Request for relief

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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